REMARKS

Status of the Claims

Claims 1-21 are pending. Claims 9, 11 and 16 have been withdrawn in response to a restriction requirement. Applicants reserve the right to prosecute claims 9, 11 and 16 in one or more divisional applications.

Claims 1 and 14 have been amended to insert a "degrees" symbol after 37±0.5. Additionally, claims 1 and 14 have been amended to recite that the formulation is "an oral" hydrophilic matrix formulation. Claim 19 has been amended to correct a spelling error. Claim 19 has been amended to better define the claimed invention. Claim 20 has been amended to change its dependency from claim 22 (which is non-existent) to claim 19. No new matter has been added as a result of any of these amendments.

Claim Rejections – 35 U.S.C. Section 112

Claims 1-8, 10, 12-15 and 17-21 are rejected under 35 U.S.C. Section 112, first paragraph, as not being enabling. Specifically, the Examiner argues that the specification is enabling for oral hydrophilic matrix formulations but does not provide enablement for any hydrophilic matrix (emphasis added). In support of his argument, the Examiner reviews each of the factors described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Applicants respectfully traverse.

While not agreeing with the Examiner, in order to expedite prosecution, claims 1 and 14 have been amended to recite "an oral" hydrophilic matrix formulation. Dependent claims 2-8, 12, 17 and 19 all (ultimately), refer back to claim 1. Claim 15 is dependent on claim 14. Claim 21 is dependent on claim 19. In view of this amendment, this rejection is now moot and should be withdrawn.

Claim 20 is rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite. Specifically, the Examiner says that claim 20 depends on claim 22, which is not present. Applicants thank the Examiner for catching this typographical error. Claim 20 has been

amended to change its dependency from claim 22 (which is nonexistent) to claim 19. In view of this amendment, this rejection is now moot and should be withdrawn.

Double Patenting

Claims 1-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over: (1) claims 1-16 of U.S. Patent No. 6,419,953; (2) claims 1-8 of U.S. Patent No. 6,511,678; (3) claims 1-7 of U.S. Patent No. 6,528,090; (4) 1-2 of U.S. Patent No. 6,528,091; (5) U.S. Patent No. 6,720,004; and (6) 1-17 of U.S. Patent No. 6,713,086.

Applicants which to hold this rejection in abeyance until notification from the Examiner of allowable subject matter. Upon receipt from the Examiner of allowable subject matter, Applicants will file the appropriate terminal disclaimers to obviate the above rejections.

Claim Rejections – 35 U.S.C. Section 103

Claims 1-8, 10, 12-15 and 17-21 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 4,913,906.

According to the Examiner, the '906 patent teaches a composition for the controlled release of salts of valproic acid that comprise 10-80% of the active agent and polymer additives such as methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcelluose and polyvinylpyrrolidone, with hydroxypropylcellulose being preferred. According to the Examiner, the amount of hydroxypropylcellulose is calculated to be up to 50% in the composition and the controlled release formulation results in sustained action of the drug with a small fluctuation of the plasma level over a prolonged period of time. Moreover, the Examiner says that the composition is a once a day oral formulation that delivers the drug for 24 hours and shows about a 97% dissolution rate profile after 24 hours. Also, divalproex sodium is disclosed as one of the salts of valproic acid and that valproate is used to treat epilepsy.

The Examiner admits that the '906 patent does not explicitly teach the same dissolution profile as the claimed invention; however, the Examiner states that it is expected that the formulation of the prior art that contains the same amount of drug and polymer would provide the same dissolution profile as the instantly claimed invention. Thereupon, according to the

Examiner it would have been obvious to one skilled in the art at the time of the invention to "deliver once a day oral formulation comprising valproic acid salts and hydrophilic polymer as disclosed by US '906, and select the salt and the polymer that provide the sustained controlled release of the drug to provide dissolution profile according to specific patient need, motivated by the teaching of US '906 that controlled release formulation results in sustained action of the drug with small fluctuation of the plasma level over prolonged period of time, with reasonable expectation of having once a day formulation comprising divalproex sodium and hydrophilic polymer that provides sustained release of the drug with small fluctuation of the plasma level over prolonged period of time to provide dissolution profile that is best controls the patient epileptic conditions" (Office Action, page 11). Applicants respectfully traverse.

As the Examiner admits, the '906 patent does not explicitly teach the same dissolution profile as the claimed invention. This is a significant difference between the prior art and the claimed invention. As discussed in Applicants' application, the claimed formulation exhibits significant advantages over the sustained release valproate formulations of the prior art. Specifically, the claimed formulation minimizes the variation between peak and trough plasma levels of valproate over a 24 hour dosing period and the claimed formulation follows a zero-order release pattern thereby producing essentially flat plasma levels of valproate, once steady-state levels have been achieved. This results in a significantly lower incidence of side effects for patients who are prescribed these formulation when compared to the prior art formulations.

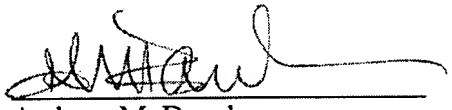
Applicants submit that the Examiner has failed to show that one skilled in the art would have had a reasonable expectation of success based on the '906 patent of arriving at the claimed invention. Applicants submit that while it may have been "obvious to try" to make the claimed formulation based on the prior art, that the claimed invention is not obvious because making efficacious and controlled release formulations involves varying a number of different parameters as well as trying a numerous possible choices. In the case of claimed formulation, the '906 patent simply does not provide any indication of which parameters are critical nor does it provide any direction as to which of the many choices are likely to be successful in order to result in a controlled release formulation of divalproex sodium having the claimed dissolution profile that could be administered once-per-day with significantly lower incidences of side effects for patients.

In view thereof, Applicants submit that the rejection is improper and should be withdrawn.

REQUEST FOR RECONSIDERATION

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account number 01-0025

Respectfully submitted,
Y. Qui, et al.



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